

AMENDMENTS TO THE CLAIMS

Claim 1 (cancelled)

Claim 2 (previously presented): A water soluble tin mesoporphyrin compound comprising a tin mesoporphyrin complexed with at least one amino acid, wherein the compound is water soluble.

Claim 3 (previously presented): The water soluble tin mesoporphyrin compound of claim 2, wherein the compound is in liquid or solid form.

Claim 4 (previously presented): The water soluble tin mesoporphyrin compound of claim 2, wherein the amino acid is selected from the group consisting of arginine, glycine, alanine, leucine, serine, lysine, histidine, phenylalanine, tyrosine and combinations thereof.

Claim 5 (previously presented): A pharmaceutical formulation comprising a water soluble tin mesoporphyrin compound comprising a tin mesoporphyrin complexed with at least one amino acid and at least one pharmaceutically acceptable carrier, wherein the compound is water soluble.

Claims 6-7 (cancelled)

Claim 8 (previously presented): The pharmaceutical formulation of claim 5, wherein the water soluble compound is in liquid or solid form.

Claim 9 (previously presented): The pharmaceutical formulation of claim 5, wherein the amino acid is selected from the group consisting of arginine, glycine, alanine, leucine, serine, lysine, histidine, phenylalanine, tyrosine and combinations thereof.

Claim 10 (previously presented): The pharmaceutical formulation of claim 5, wherein the formulation contains between about 0.1 and about 50 mg of tin mesoporphyrin dichloride.

Claim 11 (previously presented): A method comprising mixing a tin mesoporphyrin with at least one amino acid, wherein the resulting complex is water soluble.

Claim 12 (previously presented): The method of claim 11, wherein mixing is performed in a basic solution.

Claim 13 (previously presented): The method of claim 12, wherein the solution comprises an aqueous solution of sodium hydroxide.

Claim 14 (previously presented): The method of claim 12, wherein the amino acid is selected from the group consisting of arginine, glycine, alanine, leucine, serine, lysine, histidine, phenylalanine, tyrosine and combinations thereof.

Claim 15 (previously presented): The method of claim 12, wherein the ratio of the tin mesoporphyrin to amino acid is at least about 2:1.

Claim 16 (previously presented): The method of claim 14, wherein the ratio of the tin mesoporphyrin to basic solution is at least about 1:3.

Claim 17 (previously presented): The method of claim 12, further comprising filtering the solution to obtain a solid or a pharmaceutically acceptable liquid.

Claim 18 (previously presented): The method of claim 17, wherein when the filtered product is a solid, further comprising vacuum drying the solid.

Claim 19 (previously presented): The method of claim 11, wherein the tin mesoporphyrin comprises a tin mesoporphyrin halide.

Claim 20 (previously presented): The method of claim 19, wherein the halide includes tin mesoporphyrin dichloride.

Claim 21 (previously presented): The method of claim 19, further comprising, before the mixing step, the steps of subjecting a hemin to a catalytic hydrogenation, recovering a formate salt of the resulting mesoporphyrin, drying the recovered formate salt of the mesoporphyrin, and subjecting the mesoporphyrin formate to a chemical metal insertion process reaction with a metal halide compound under buffered reaction conditions to produce the tin mesoporphyrin halide.

Claim 22 (previously presented): A pharmaceutical formulation including the water soluble complex of the tin mesoporphyrin and the at least one amino acid formed by the method of claim 11 mixed with at least one pharmaceutically acceptable carrier.

Claim 23 (previously presented): A method of preparing a water-soluble complex of a metal mesoporphyrin, which comprises:

heating a reaction mixture of a hemin and a hydrogenation catalyst to a first temperature for a first period of time;

supplying hydrogen to the reaction mixture;

subjecting the reaction mixture to a second temperature for a second period of time;

recovering a formate salt from the reaction mixture and drying the salt to obtain a mesoporphyrin IX formate;

subjecting the mesoporphyrin IX formate to a chemical metal insertion process reaction with a metal halide compound under reaction conditions to produce a metal mesoporphyrin halide; and

reacting the metal mesoporphyrin halide with at least one amino acid in the presence of a basic solution to produce a water-soluble complex of a metal mesoporphyrin and the at least one amino acid.

Claim 24 (previously presented): The method of claim 23, wherein the first temperature is higher than the second temperature.

Claim 25 (previously presented): The method of claim 24, wherein the first temperature is between about 85-95°C.

Claim 26 (previously presented): The method of claim 25, further comprising adding an acid to the reaction mixture of hemin and hydrogenation catalyst; and subjecting the reaction mixture to hydrogen pressure for at least one hour.

Claim 27 (previously presented): The method of claim 26, wherein the second temperature is between about 45-50°C and the second period of time is at least about 3 hours.

Claim 28 (previously presented): The method of claim 27, wherein subjecting the mesoporphyrin IX formate to a chemical metal insertion process reaction with a metal halide compound is in the presence of an oxidant under buffered, acidic reaction conditions.

Claim 29 (previously presented): A pharmaceutical formulation including the water-soluble complex of the metal mesoporphyrin and the at least one amino acid formed by the method of claim 23, wherein the metal mesoporphyrin is a tin mesoporphyrin.

Claim 30 (previously presented): The pharmaceutical formulation of claim 29, wherein the metal mesoporphyrin comprises tin mesoporphyrin dichloride.

Claim 31 (previously presented): The method of claim 23, wherein the amino acid is selected from the group consisting of arginine, glycine, alanine, leucine, serine, lysine, histidine, phenylalanine, tyrosine and combinations thereof.

Claims 32-33 (cancelled)

Claim 34 (previously presented): A method of treating a human being with a heme metabolism disorder comprising administering to said human being a pharmaceutically effective amount of a water soluble tin mesoporphyrin compound comprising a tin mesoporphyrin complexed with at least one amino acid.

Claim 35 (previously presented): The method of claim 34, wherein the amino acid is selected from the group consisting of arginine, glycine, alanine, leucine, serine, lysine, histidine, phenylalanine, tyrosine and combinations thereof.

Claim 36 (previously presented): The method of claim 35, wherein the disorder is hyperbilirubinemia.

Claim 37 (previously presented): The method of claim 35, wherein the disorder is psoriasis.